



1FW 1624

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Young Mi Choi-Sledeski, et al.**

Application No.: **09/918,039**

Examiner: **T.N. Truong**

Filed: **July 30, 2001**

Group Art Unit: **1624**

For: **SULFONIC ACID OR SULFONYLAMINO N-(HETEROARALKYL)
AZAHETERYCYCLYLAMIDE COMPOUNDS**

Attorney Docket No.: **P24,450-E US1**

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July 1, 2006

Peter J. Butch III
Peter J. Butch III

Mail Stop Petitions
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR SUSPENSION OF ACTION UNDER 37 C.F.R. § 1.103(a)

Sir:

This is a Petition to have prosecution relative to the above-identified application suspended for the period of three months.

Claims 35-41 are pending herein.

On June 27, 2005, a Restriction Requirement (attached hereto as "Attachment A") was mailed by the U.S. Patent and Trademark Office relative to the instant application. The Restriction Requirement divided claims 35-41 into 16 groups. In the paper filed September 22, 2005 (attached hereto as "Attachment B"), Applicants traversed the Restriction Requirement, arguing that it was improper and requesting that it be reconsidered and drawn. In an Office Action mailed December 30, 2005 (attached hereto as "Attachment C"), the Examiner made the Restriction Requirement final. Furthermore, the December 30, Office Action set forth two rejections of the claims under 35 U.S.C. § 112. On June 30, 2006,

Applicants filed a Petition under 37 C.F.R. §1.144 Requesting Withdrawal of Restriction Requirement (attached hereto as "Attachment D"). On the same date, Applicants also filed an Amendment in response to the December 30 Office Action (attached hereto as "Attachment E").

In the Amendment, claims 35 and 39 were amended and arguments were made that Applicants believe will overcome the §112 rejections set forth in the December 30 Office Action. If the Rejections are overcome, the application will proceed to issue. However, because of the complexity of the Restriction Requirement, Applicants are concerned that the application will go to issue before the decision on the Petition under 37 C.F.R. §1.144 is reached and likely before resolution of the matter.

As pointed out above, the claims were divided into 16 groups. This is prejudicial to Applicants and to the public interest because the Restriction Requirement significantly impairs the notice function of the claims because of the numerous groupings of claims and numerous patents that are likely to issue from the Restriction Requirement. In addition to impairment of the notice function, the number of patents issuing from the Restriction Requirement complicates patent enforcement for Applicants.

In essence, the sole issue here is the Restriction Requirement and no other issues.

Thus, for the foregoing reasons, Applicants respectfully request that prosecution relative to the above-identified application be suspended.

Enclosed is payment of the required petition fee under 37 C.F.R. § 1.17(h) in the amount of \$130.00. If any additional fees are due, please charge them to Deposit Account No. 19-5425.

July 1, 2006

Respectfully submitted,


Peter J. Butch III

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,039	07/30/2001	Yong Mi Choi-Sledeski	P24450-E US1	3370

7590 06/27/2005

Synnestvedt & Lechner LLP
2600 Aramark Tower
1101 Market Street
Philadelphia, PA 19107-2950

EXAMINER

TRUONG, TAMTHOM NGO

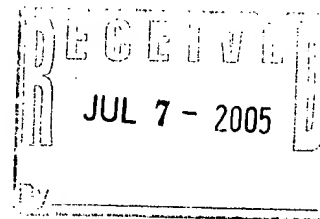
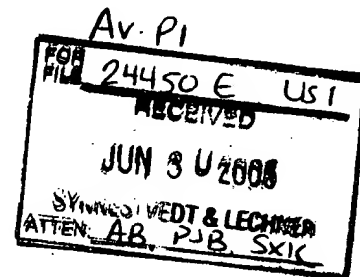
ART UNIT PAPER NUMBER

1624

DATE MAILED: 06/27/2005

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Please find below and/or attached an Office communication concerning this application or proceeding.



Office Action Summary

Application No.

09/918,039

Applicant(s)

CHOI-SLEDESKI ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 35-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment of 4-07-05 has been considered. The election with traverse of Group 17 (or XVII) is acknowledged. Group 17 was indicated with further restriction previously. Therefore, Group 17 is further divided according to the different combination of substituents of the claimed formula.

Claims 1-34, and 42 are cancelled.

Claims 35-41 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar¹ is pyrrolo[2,3-*c*]pyridinyl;

R₂ is SO₂-phenyl, or SO₂-naphthyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;

classified in classes 514, 546, various subclasses depending on substituents.

2. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

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Ar^1 is pyrrolo[2,3-c]pyridinyl;

R_2 is SO_2 -(5-membered heteroaryl or heterocyclyl);

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;

classified in classes 514, 546, various subclasses depending on substituents.

3. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[2,3-c]pyridinyl;

R_2 is SO_2 -(6-membered heteroaryl)

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;

classified in classes 514, 546, various subclasses depending on substituents.

4. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[2,3-c]pyridinyl;

R_2 is SO_2 -quinolinyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;

classified in classes 514, 546, various subclasses depending on substituents.

5. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[2,3-c]pyridinyl;

R_2 is SO_2 -benzopyranyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;

classified in classes 514, 546, various subclasses depending on substituents.

6. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[2,3-b]pyridinyl;

R_2 is SO_2 -phenyl, or SO_2 -naphthyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;

classified in classes 514, 546, various subclasses depending on substituents.

7. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[2,3-b]pyridinyl;

R_2 is SO_2 -(5-membered heteroaryl or heterocyclyl);

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in classes 514, 546, various subclasses depending on substituents.

8. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[2,3-b]pyridinyl;

R_2 is SO_2 -(6-membered heteroaryl)

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in classes 514, 546, various subclasses depending on substituents.

9. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[2,3-b]pyridinyl;

R_2 is SO_2 -quinolinyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in classes 514, 546, various subclasses depending on substituents.

10. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar¹ is pyrrolo[2,3-b]pyridinyl;

R₂ is SO₂-benzopyranyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;
classified in classes 514, 546, various subclasses depending on substituents.

11. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar¹ is pyrrolo[3,2-c]pyridinyl;

R₂ is SO₂-phenyl, or SO₂-naphthyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;
classified in classes 514, 546, various subclasses depending on substituents.

12. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar¹ is pyrrolo[3,2-c]pyridinyl;

R₂ is SO₂-(5-membered heteroaryl or heterocyclyl);

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In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in classes 514, 546, various subclasses depending on substituents.

13. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[3,2-c]pyridinyl;

R_2 is SO_2 -(6-membered heteroaryl)

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in classes 514, 546, various subclasses depending on substituents.

14. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar^1 is pyrrolo[3,2-c]pyridinyl;

R_2 is SO_2 -quinolinyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in classes 514, 546, various subclasses depending on substituents.

15. Claims 35-41 (in part) drawn a method of treatment using compounds of the claimed formula, and pharmaceutical composition thereof, wherein:

Ar¹ is pyrrolo[3,2-c]pyridinyl;

R₂ is SO₂-benzopyranyl;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents;
classified in classes 514, 546, various subclasses depending on substituents.

16. Claims 35-41 (in part) drawn a method of treatment using the remaining compounds of the claimed formula, and pharmaceutical composition thereof, wherein the combination of Ar¹ and R₂ is not in the above groups, in combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in classes 514, 546, various subclasses depending on substituents. Further restriction will be required if this group is elected.

The inventions are distinct, each from the other because of the following reasons:

- a. Inventions groups 1-16 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In

the instant case the combinations of rings represented by Ar^1 , R_2 and the pyrrolidinone ring define the different inventions.

b. Although all groups share the ring of *pyrrolidinone*, said ring alone does not sufficiently define the invention, and does not contribute to the art. Therefore, it is the combination of the *pyrrolidinone* with Ar^1 and R_2 that gives each group a distinct physical, chemical and/or biological properties, and thus sets apart the compounds of one group from those of the others. Thus, a reference that anticipated, or rendered obvious one group would not do so to the others, and so, a separate search is required for each group.

Because these inventions are distinct for the reasons given above and the search required for Group 1 is not required for Group 2-17, and the search for all 17 distinct invention would impose a serious burden upon the examiner in charge of this invention, restriction for examination purposes as indicated is proper.

Due to the complexity of the grouping, the restriction is presented in writing.

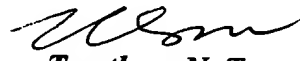
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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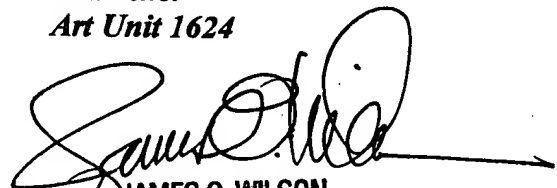
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (10:00-6:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Tamthom N. Truong
Examiner
Art Unit 1624

6-22-05


JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

ATTACHMENT B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Young Mi Choi-Sledeski, et al.**

Application No. **09/918,039**

Examiner: **T.N. Truong**

Filed: **July 30, 2001**

Group Art Unit: **1624**

For: **SULFONIC ACID OR SULFONYLAMINO N-(HETEROARALKYL)
AZAHETERYCYCLYLAMIDE COMPOUNDS**

Attorney Docket No. **P24,450-E US1**

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Nazia Zamir

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY PURSUANT TO 37 C.F.R. § 1.111

This is in response to the Office Action mailed June 27, 2005, having a shortened period of response expiring on July 27, 2005. Claims 35-41 are pending in this application and are subject to Restriction and Species Election Requirements. Applicants traverse hereby the Examiner's Requirements for Restriction and Species Election and respectfully request reconsideration and withdrawal of both Requirements.

The Examiner requires restriction between the following groups of claims:

- I. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2, 3-

c] pyridinyl and R₂ is SO₂-phenyl or SO₂-naphthyl in combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agent, antiplatelet agents and fibrinolytic agents, classified in classes 514 and 546 among various subclasses depending upon substituents.

- II. Claims 35-41(in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-c] pyridinyl and R₂ is SO₂-(5-membered heteroaryl or heterocyclyl) in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.
- III. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-c] pyridinyl and R₂ is SO₂-(6-member heteroaryl) in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.
- IV. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-c] pyridinyl and R₂ is SO₂-quinolinyl in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.
- V. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-c] pyridinyl and R₂ is SO₂ - benzopyranyl in combination with the aforementioned agents of Group I classified in classes 514 and 546 among various subclasses depending upon substituents.

- VI. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-b] pyridinyl and R₂ is SO₂-phenyl or SO₂-naphthyl in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.
- VII. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-b] pyridinyl and R₂ is SO₂-(5-membered heteroaryl or heterocyclyl) in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.
- VIII. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-b] pyridinyl and R₂ is SO₂-(6-membered heteroaryl) in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.
- IX. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-b] pyridinyl and R₂ is SO₂-quinolinyl in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.
- X. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-b] pyridinyl and R is SO₂-benzopyranyl in combination with the aforementioned agents of Group I classified in classes in 514 and 546 among various subclasses depending upon substituents.

- XI. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [2,3-c] pyridinyl and R₂ is SO₂-phenyl or SO – naphthyl in combination with the aforementioned agents of Group I, classified in classes in 514 and 546 among various subclasses depending upon substituents.
- XII. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [3,2-c] pyridinyl and R₂ is SO₂-(5-heteroaryl or heterocyclyl) in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.
- XIII. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [3,2-c] pyridinyl and R₂ is SO₂-(6-heteroaryl) in combination with the aforementioned agents of Group I, classified in classes in 514 and 546 among various subclasses depending upon substituents.
- XIV. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [3,2-c] pyridinyl and R₂ is SO₂-quinolinyl in combination with the aforementioned agents of Group I, classified in classes in 514 and 546 among various subclasses depending upon substituents.
- XV. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which Ar¹ is pyrrolo [3,2-c] pyridinyl and R₂ is SO₂-benzopyramyl in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.

XVI. Claims 35-41 (in part) drawn to a method of treatment using compounds of Formula I and pharmaceutical compositions thereof in which the combination of Ar^1 and R_2 is not in Group I-XV in, in combination with the aforementioned agents of Group I, classified in classes 514 and 546 among various subclasses depending upon substituents.

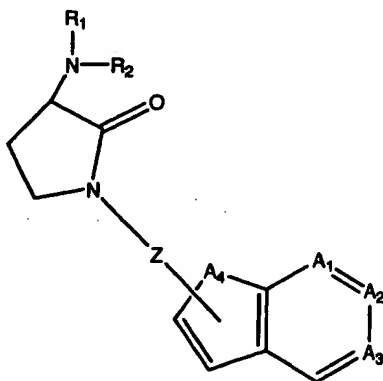
Applicants submit that the Election and Restriction Requirements are improper for dividing Applicants' Markush claim in contravention to the Requirements of MPEP § 803.02 and case law.

MPEP § 803.02 Considerations

In particular, MPEP § 803.02 provides that there is no basis for requiring election or restriction of a Markush claimed invention where two factors are met, i.e.,

... compounds included within a Markush Group (1) share a common utility and (2) share a substantial structural feature ...

Applicant's Markush claimed in meets the aforesaid factors. That is: (A) their compounds have a substantial structural feature, i.e., the formula:



(B) their compounds share a common utility, i.e., being useful for treating physiological disorders capable of being modulated by inhibiting an activity of Factor Xa. Thus, the present Election and Restriction Requirements are improper. There is also no basis for the present

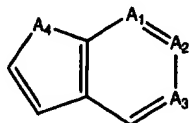
Election and Restriction Requirements because the Examiner has failed to address the above two factors of MPEP § 803.02 in making the Election and Restriction Requirements.

Case Law Considerations

The present Restriction Requirement is based upon variation in R_2 and Ar^1 substituents on a pyrrolidinone nucleus. In Re Harnisch, 206 U.S.P.Q. 300 (CCPA 1980) and cases related thereto, including Ex parte Dahlen and Zwilgmeyer, 42 U.S.P.Q. 208 (Bd. App. 1938), Ex parte Brouard et al., 201 U.S.P.Q. 538 (Bd. App. 1976) and Ex parte Holt and Randell, 214 U.S.P.Q. 381 (Bd. App. 1982) do not support the present Election and Restriction Requirements. In In re Harnisch, 206 U.S.P.Q. 300 (CCPA 1980), the court reiterated that the grouping of compounds having the same nuclei but side chains wherein there was a wide variation was proper if the compounds all belong to the same genus having a community of properties justifying their grouping. In re Harnisch, 206 U.S.P.Q. at 305. The present Restriction Requirement is therefore explicitly contravened by In re Harnisch. The Examiner seeks to restrict a grouping of compounds with a common nucleus and community of properties because the Examiner considers two of the substituent groups, R_2 and Ar^1 , to widely vary. However, according to In re Harnisch, this is not a proper basis for Restriction.

Furthermore, there is not even "wide variation" in the substituent group identified by the Examiner as Ar^1 . The only possible variations of the Ar^1 group identified by the Examiner is three isomers of a pyrrolopyridine fused ring structure.

In addition, applicants note that there is no Ar^1 group in the presently pending claims for the Examiner to restrict. In the amendment submitted April 4, 2005, the Ar^1 group was replaced with a fused ring structure having the formula:

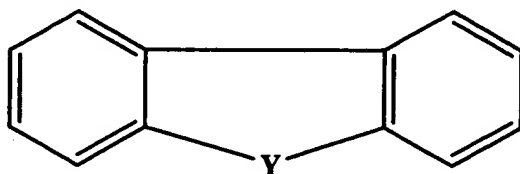


wherein one of A_1, A_2 and A_3 is N and the other two are CH and A_4 is NR_{11} . The purpose of replacing Ar^1 with this structure was to illustrate that the common nucleus having a community of properties in the claimed structure is a pyrrolidinone linked by a divalent "Z" to a pyrrolopyridine fused ring structure that can vary isomerically. Viewed in this manner, there is unity of invention between the two rings, so that restriction of the pyrrolopyridine ring is improper. Furthermore, because the R_2 group is a side chain for which wide variation is permitted pursuant to In re Harnisch, restriction of the R_2 group is also improper.

Nevertheless, even assuming the Examiner's identification of the pyrrolidinone ring as the common nucleus, variation among three Ar^1 substituents and the R_2 side groups does not provide an adequate basis for restriction under In re Harnisch because, despite such variation, a genus of compounds can still be identified having a community of properties that justify their grouping. Therefore, the present Election and Restriction Requirements are improper because they seek election among substituents attached to a common nucleus defining a genus of compounds with a community of properties.

Furthermore, there is no basis for the present Election and Restriction Requirements because the Examiner has failed to address the above the above Harnisch factors.

In Ex parte Dahlen and Zwilgmeyer, 42 U.S.P.Q. 208 (Bd. App. 1938), a Markush compound of the formula:



was found to be proper when Y was defined as a bivalent bridge radical that was further defined in Markush format as consisting of the following 12 members: $-CH_2-$, $-CO-$, $-C=C-$, $-CH_2CH_2-$, $-NH-$, $-N-Alkyl-$, $-O-$, $-S-$, $-N=N-$, $-N=N-$, $-N=NO-$, $-SO_2-$, $-COCO-$. Particularly noteworthy regarding that compound was that the Markush grouping was found to be acceptable even though the variable Y provided for variations in the size and classes of tricyclic ring systems, i.e., the central ring could be defined to have a ring size of 5 or 6 members that included a ring selected

from a cyclopentadienyl ring, a cyclohexadienyl ring, a phenyl ring, and one of four different heteroaryl rings (pyrrolyl, furanyl, thienyl or pyridazinyl). This demonstrates that the present restriction among pyrrolopyridinyl ring isomers is improper because it gives rise to exceptionally less variability in the classes of compounds encompassed by the genus defined by the core pyrrolidinone ring and R_2 and Ar^1 substituents. Accordingly, Applicants submit that Ex parte Dahlen and Zwilgmeyer supports that there is no basis for Election or Restriction in the instant case even though there is variability among pyrrolopyridine fused ring isomers.

Furthermore, Ex parte Brouard et al., 201 U.S.P.Q. 538(Bd. App. 1976) state that “... the fact that different fields of search are involved does not establish that the Markush group is improper.” In particular, six different fields of search were not sufficient in Ex parte Brouard et al., to establish a proper Election or Restriction of the Markush group therein. Likewise, because there are only two different fields (514 and 546) related to the presently restricted groups I-XVI of the invention, this should not be viewed as providing the proper basis of support for either Election or Restriction.

In view of the aforesaid, Applicants submit that Applicant's invention is not properly subject to Restriction or Election.

Applicants also submit that the applicable standard under which claims subject to Restriction are evaluated should not include whether there would be a serious burden on the Examiner were Restriction not required, as suggested by MPEP § 803.¹ Rather, the standard should align with the holding of In re Harnisch, 206 U.S.P.Q. 300 (CCPA 1980).

¹ See MPEP § 803, Restriction-When Proper states: “Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04-§ 806.04(i) or distinct (MPEP § 806.05 – § 806.05(i)). If the search and examination can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS. There are two criteria for proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent (See MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (See MPEP § 806.05- § 806.05(i)); and (B) There must be a serious burden on the Examiner if Restriction is required (See MPEP § 803.02, § 806.04(a) – § 806.04(i), § 808.01(a), and § 808.02).”

Not only has the Examiner disregarded In re Harnisch and related cases such as Ex parte Dahlen and Zwilgmeyer, 42 U.S.P.Q. 208 and Ex parte Brouard et al. 201 U.S.P.Q. 538, but the present Election and Restriction Requirements directly contravene the holding of Ex parte Holt and Randell, 214 U.S.P.Q. 381.

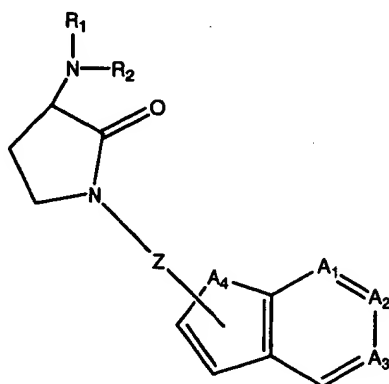
The PTO Board Appeals in Ex parte Holt and Randell, 214 U.S.P.Q. 381, held that there is no basis for a Markush Rejection where “the Examiner dissects the molecule into core and pendent substituents and then concludes that variable cores inherently constituted an improper Markush group.” Id. at 386. This holding is supported by Harnisch language that requires a Markush grouping analysis be conducted based upon a molecule “as a whole,” and not as a separately dissected parts of an invention, or separately dissected sections of claims when analyzing Markush-type claims.

In the instant case, the Examiner has: (1) misidentified the common structural feature pyrrolidinone as being the “core” of Applicants’ claimed invention; (2) inappropriately truncated a common structural feature (pyrrolopyridine) that Applicants submit is also part of the “core” of their claimed invention; and (3) based the Restriction solely on substituents on the misidentified common structure (i.e., substituents that are actually part of the common structural core serve as the basis for the Restriction.)

Regarding the misidentified core, the Examiner states, “all groups share the ring of *pyrrolidinone* [emphasis by Examiner].” See Office Action at page 9. However, Applicants submit their claimed compounds are not pyrrolidinones, but in fact are pyrrolidinone-pyrrolopyridines.

Consequently, the Examiner has misdirected the basis for the search and Restriction Requirement by dissecting the molecule into a smaller core and pendent substituents to improperly conclude that the core of the molecule only includes a pyrrolidinone ring substituted by one of three pyrrolopyridine isomers, as well as R₂ substituents.

Applicants submit that the Examiner's search should have been based upon the following structural "core:"



and not just the pyrrolidinone portion of that core. Despite the A₁- A₄ variation within the pyrrolopyridine portion of the core, as well as the "Z" bridge variation between pyrrolidinone and pyrrolopyridine rings, a search based upon this structural core will not present an undue burden to the Examiner. As the Examiner acknowledges, there are only two classes in which compounds having this core are classified.

In summary, the pyrrolopyridine ring is part of the common structural core claimed and not a substituent subject to Restriction. Even if it were a substituent, the three isomers claimed do not vary so widely as to prohibit their grouping pursuant to In re Harnisch. Finally, because R₂ is a substituent of the core ring identified by the Examiner, and because variation among the R₂ groups does not affect the common properties of the compounds claimed, Restriction among the R₂ groups is also improper pursuant to In re Harnisch.

In view of the aforesaid comments regarding MPEP § 803.02 and case law cited by Applicants, Applicants request that Applicants' arguments regarding the impropriety of the Election and Restriction Requirements be specifically addressed on both the bases of MPEP § 803.02 and case law if the Election and Restriction Requirements are maintained. Furthermore, Applicants request they be provided with the opportunity to respond to any new bases made in support of the Election and Restriction Requirements before the Election and Restriction Requirements are made final.

Applicants: Young Mi Choi-Sledeski, et al.
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Docket No. P24,450-E US1

Provisional Election

To comply with the Examiner's Election Requirements, Applicant provisionally elect, with traverse, Group XVI, and elect as the species within that group thieno[3,2-b] pyridine-2-sulfonic acid [2-oxo-1-(1 H-pyrrolo[2,3-c]pyridin-2-ylmethyl)-pyrrolidin-3-(S)-yl]-amide. The elected species is depicted in Example 48. Applicants affirm their right to file one or more Divisional Applications with respect to any of the non-elected subject matter.

If there are any additional charges in connection with this response, the Examiner is authorized to charge Applicants' Deposit Account No. 19-5425 therefore.

Respectfully Submitted,

Date:

September 22, 2005



Peter J. Butch III, Esq.
Registration No. 32,203

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ATTACHMENT C

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09/918,039	07/30/2001	Yong Mi Choi-Sledeski	P24450-E USI	3370

7590 12/30/2005
Synnestvedt & Lechner LLP
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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 12/30/2005

ENTERED COMPUTER

3-30-06

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED
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By _____

Office Action Summary

Application No.

09/918,039

Applicant(s)

CHOI-SLEDESKI ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

In the reply of 9-26-05, applicants have elected with traverse the subject matter of group 16 and the species in Example 48.

The traversal is on the grounds that the compounds have a substantial structural feature of the formula as recited in claim 35, and that the compounds have a common utility (i.e., inhibiting an activity of Factor Xa).

Applicant asserted that the original Ar¹ has been replaced with a *bicycle* having ring atoms of A₁, A₂, A₃ and A₄. Thus, there is unity of invention.

Applicant's traversal is not found persuasive for the following reasons:

- The *bicyclic* core of A₁-A₄ can vary in structure depending on the position of A₁-A₃. The core of *pyrrolo[2,3-b]pyridine* is definitely not obvious over the core of *pyrrolo[3,2-c]pyridine*, nor it is obvious over *pyrrolo[2,3-c]pyridine*. Therefore, the bicyclic core is not a special technical feature that is common to compounds of all the groups.
- Furthermore, variables R₁ and R₂ represent a large number of functional groups and ring systems. The combination of which would definitely set apart compounds of one group from those of the others.
- Although all groups share the *pyrrolidinone* ring, such a ring alone does not sufficiently define the invention, and is not a contribution to the art.

- Therefore, it is the combination of at least *pyrrolidinone*, *bicyclic core*, and R_2 that gives compounds in each group their unique physical and chemical properties as well as biological activity.

Because Group 16 was indicated with further restriction, it is therefore, divided as below:

Group 16a: Claims 35-41 (in part) drawn to a pharmaceutical composition, and a method of treatment using a compound of the formula recited in claim 35 wherein:

- The bicyclic system having A_1-A_4 is *pyrrolo[2,3-*c*]pyridine*;
- R_2 is $R_3S(O)_p$; $p = 2$;
- R_3 is *thieno[3,2-*b*]pyridine*
- X_3 and one of X_1 and X_{1a} do not form a ring (i.e., no fused pyrrolidinone).

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in class 514, and 546, various subclasses depending on substituents.

Group 16b: Claims 35-41 (in part) drawn to a pharmaceutical composition and a method of treatment using a compound of the formula recited in claim 35 wherein:

- The bicyclic system having A_1-A_4 is **not** *pyrrolo[2,3-*b*]pyridine*, *pyrrolo[3,2-*c*]pyridine*, or *pyrrolo[2,3-*c*]pyridine*;
- R_2 is **not** $R_3S(O)_p$; $p = 2$;
- R_3 is **not** *thieno[3,2-*b*]pyridine*;

In combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents; classified in class 514, and 546, various subclasses depending on substituents.

The elected species falls within Group 16a, and thus, claims 35-41 are considered to the extent of the subject matter in Group 16a.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 35-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a. Claim 35 recites the disorder as "*a physiological disorder capable of being modulated by inhibiting an activity of Factor Xa...*" which has indefinite metes and bounds because it reads on a disorder with too little clotting (e.g., hemophilia), and also a disorder with too much clotting (e.g., embolism). Besides, the specification associates factor Xa with more diseases than just blood coagulation. Thus, it is unclear what other diseases are intended in the method of claim 35.

- b. Claims 35 and 39 recite the positions of Z which is "positions 2 to 7" on the pyrrolopyridine ring. However, it is noted that the pyrrolopyridine ring is not numbered the way recognized by the art. That is, as exemplified by the elected species, the 2-position is on the pyrrolo ring, and not on the pyridine ring. Such an unconventional way of numbering appears to be inconsistent with the way recognized by the art.
- c. Claim 38 lacks antecedent basis because it depends on claim 35, but recites "prodrugs, derivatives and analogs thereof" which are not recited in claim 35.
- d. Claim 39 is a pharmaceutical composition claim comprising additional therapeutic agent(s). However, it is not clear if the additional agent(s) are formulated together (in a tablet, capsule or injectable) with the claimed compound, or if it is in separate formulations, but is given at the same time (e.g, separate tablets in the same blister pak).
- e. Claims 36-38, 40 and 41 are rejected as being dependent on either claim 35 or 39, and carrying over the indefinite limitations.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Enablement:** Claims 35-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following factors have been considered in the determination of an enabling disclosure:

- (1) The breadth of the claims;
- (2) The amount of direction or guidance presented;
- (3) The state of the prior art;
- (4) The relative skill of those in the art;
- (5) The predictability or unpredictability of the art;
- (6) The quantity of experimentation necessary;

[See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also *In re Wands*, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims:

Claim 35 recites: "A method for treating...a physiological disorder capable of being modulated by inhibiting an activity of Factor Xa comprising administering to the patient a therapeutically effective amount of a pyrrolopyridine compound having the structure...wherein said compound is administered in combination with at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents, and fibrinolytic agents."

The action intended by the inhibition of Factor Xa includes more than anticoagulant therapy. According to the specification, such an action includes “*chronic and degenerative diseases as arthritis, cancer, atherosclerosis, restenosis post coronary angioplasty and Alzheimer’s disease...*” Thus, not only claim 35 recites broad scope of compounds, but also a broad scope of diseases as well as additional agents. Therefore, the scope of claim 35 is unduly broad.

Claims 36-38 depend on claim 35, and recite specific additional agents. However, their scopes are still unduly broad in terms of the claimed compounds, and diseases related to Factor Xa.

Like claim 35, claim 39 recites a pharmaceutical composition comprising the claimed compounds and “*at least one other agent selected from diagnostic agents, cardioprotective agents, direct thrombin inhibiting agents, anticoagulant agents, antiplatelet agents and fibrinolytic agents.*” The scope of the compounds recited in claim 39 is just as broad as that recited in claim 35. With the combination of so many agents, the scope of claim 39 is unduly broad.

Claims 40 and 41 depend on claim 39, and recite specific additional agents, but still has the broad scope of the compounds. Therefore, the scopes of claims 40 and 41 are unduly broad as well.

The amount of direction or guidance presented:

Although the specification provides the guidance for making the claimed *pyrrolo[2,3-c]pyridine* compounds, as exemplified by the elected species in Example 48. However,

regarding the activity of such a compound as inhibitor of Factor Xa, the specification does not provide any IC_{50} value of such a compound. The specification only describes bioassay procedures without disclosing any tested *pyrrolo[2,3-c]pyridine* compounds. The only compound actually tested was a compound of substituted *1,6-diaminoisoquinoline*. Although *isoquinoline* is a bicycle, its structure is not equivalent to that of *pyrrolo[2,3-c]pyridine*. Thus, the activity of *isoquinoline* cannot be extrapolated to that of *pyrrolo[2,3-c]pyridine*. As for the combination of the claimed compounds and other agents, the specification does not teach how the claimed compounds can be combined as at what dosage. Thus, the specification fails to provide sufficient guidance for one skilled in the art to make such a pharmaceutical composition as recited in claims 39-41, and use it in a broad method as recited in claims 35-38.

The state of the prior art:

Although anticoagulant agents can often be combined in the clinical setting, such a combination is often done for a short term (e.g., post-op telemetry), and with close monitoring of the prothrombin time. Some anticoagulant agents can interfere by displacing or competing with each other for protein binding, and thus, could alter the bioavailability of each other. For example, warfarin is known to alter other drug's bioavailability by competing for protein binding. While blood clot does not have a desirable effect, too little clotting could lead to hemophilia, which could be just as detrimental.

Furthermore, as evident by the teachings of **Baker et. al.** (US 5,854,268), and **Chambers et. al.** (US 5,604,240), the compounds of *pyrrolo[2,3-c]pyridine* have the activity of selective agonists of 5-HT₁ receptors, and not inhibitors of Factor Xa. Thus, the current practice of

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medicine and state of the prior arts do not seem to support the pharmaceutical composition and method of treatment recited in claims 35-41.

The relative skill of those in the art:

Even with the advanced training, the skilled clinician would have to carry out extensive research to select an effective compound from the large Markush group of formula I. Not only one has to determine an IC_{50} value, but also *in-vivo* activity to establish an LD_{50} , therapeutic index and pharmacokinetic profile for each compound. Once an effective compound is identified, the skilled clinician would have to evaluate the combination of said compound with any of the additional agents listed in claims 35-41. Given a large Markush group of the claimed formula I, and the multiple combinations, such a task would require a tremendous amount of effort, time and resource.

The predictability or unpredictability of the art & The quantity of experimentation necessary:

The pharmaceutical art has been known for its unpredictability due to various conflicting path ways, or biological factors that are sometimes genetically unique to individuals. In the instant case, the specification only describes bioassays without indicating any tested compounds of *pyrrolo[2,3-c]pyridine*. However, said description alone does not adequately guide the skilled clinician in the treatment of diseases that are allegedly related to Factor Xa which includes cancer, and Alzheimer's disease. Thus, with such a limited teaching, the skilled clinician would have to carry out undue experimentation to make a pharmaceutical composition by combining agents as recited in claims 39-41, and use it in the methods recited in claims 35-38.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

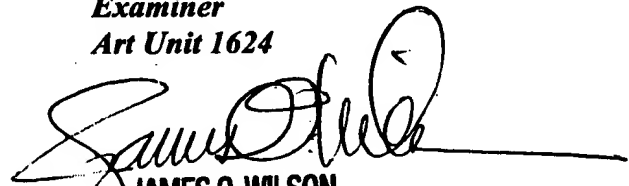
12-11-05



Tamthom N. Truong

Examiner

Art Unit 1624



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

ATTACHMENT D